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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,967	11/16/2001	Ying-Fei Wei	PF268D1C1	7962

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/987,967	Applicant(s) WEI ET AL.	
	Examiner Lorraine Spector, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 14-76 is/are pending in the application.
- 4a) Of the above claim(s) 1, 14-24, 43, 44, 68 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-41, 44-67 and 70-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 14-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9/12/2003</u> | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action:

Claims 1 and 14-76 are pending.

Restriction Requirement:

Applicant's election with traverse of Group XI in the Paper filed 9/12/2003 is acknowledged. The traversal is on the ground(s) that the examination of all groups would not be burdensome, and that rejoinder of Group XII would be required upon the finding of allowability of Group XI. With respect to the former argument, a search burden may be shown by separate classification of the claimed inventions, which was done in the restriction requirement, each such invention being separately classified. With respect to the latter argument, applicants are correct; at such time as the antibody claims are indicated as being allowable, the methods of using such will be rejoined. However, such would be premature at this time.

The requirement is still deemed proper and is there FINAL.

Claims 25-41, 44-67 and 70-76 are under consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities. Appropriate correction is required for each listed item:

- The status of the related applications to which reference is made at page 1§1 of the specification should be updated.

The Examiner acknowledges the deposit of organisms under accession numbers ATCC 97455 under terms of the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention as claimed

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in claims 64-81. The disclosed deposit is found to be in compliance with the requirements (see MPEP Chapter 2400 and 37 C.F.R. §§1.801-1.809).

Applicant is advised that should claims 27, 34, and 53 be found allowable, claims 30, 49 and 56, respectively, will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 38, 39, 64 and 65 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The Examiner is unaware of any antibodies meeting the limitations of the independent claims that would not be suitable for use in western blotting or ELISA procedures.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-41, 44-67 and 70-76 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility.

The specific asserted utility for the disclosed hHSP is that it is alleged to be a protein preferentially expressed in hematopoietic cells (hence the designation hHSP), and to be involved in some aspect of hematopoietic cell proliferation or activity. The asserted utilities for the claimed antibodies stem from their ability to bind the protein, i.e. for use in purifying or detecting the protein, (paragraph[0172] of the specification) , or as antagonists of the protein.

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The specification does not disclose any biological function associated with the protein, nor any condition for which presence of the protein would be diagnostic, nor even a single condition for which administration of antibodies that bind the protein would be desired. Accordingly, the specification seems to present an invitation to the person of ordinary skill in the art to determine what the function and/or significance of the disclosed protein is, and then to develop methods of using the antibodies which take advantage of that function or significance. In the absence of any specific assertion of utility, that is, any available use for the claimed antibodies other than for further determining the properties/characteristics of the proteins to which they bind, the Examiner finds that the invention lacks utility.

Utility must be in readily available form. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to an antibody that binds a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as hHSP protein, the claimed invention is incomplete. Merely using the antibodies to isolate the protein to which they bind does not constitute a patentable utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 25-41, 44-50, 76 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-41, 44-67 and 70-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 44 are indefinite due to the brackets surrounding the minus (“-“) sign in the third line of the claims.

Claims 50 and 76 are indefinite because one cannot obtain a chimeric, humanized or single chain antibody from an animal.

The remaining claims are rejected for depending from an indefinite claim.

Prior Art:

The prior art made of record by applicants and not relied upon is considered pertinent to applicant's disclosure.

M. Adams et al., Nature Genetics 4:373, 1993 disclose numerous sequences from a human infant brain cDNA library. Among the sequences disclosed by Adams et al. are EST69317, which has 99.2% identity to nucleotides 520-770 of SEQ ID NO: 1. No antibodies are disclosed.

Matsubara, WO95/14772 disclose a cDNA clone which has 97.4% identity to nucleotides 503-810 of SEQ ID NO: 1. No antibodies are disclosed.

U.S. Patent number 5,212,074 discloses a protein sequence which matches exactly residues 5-14 of SEQ ID NO: 2 of the instant application. See Figure 2A, second line.

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Karpusas et al. (Biochemistry 29:2213) discloses a protein sequence with a 4/5 match at residues 88-92 of SEQ ID NO: 2 of the instant application.

Advisory Information:

No claim is allowed.

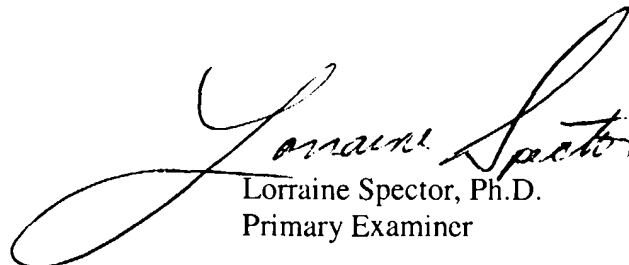
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number will be 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623. ***Effective 1/21/2004, Dr. Kunz' telephone number will be 571-272-0887.***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228. ***Effective 1/21/2004, Dr. Spector's fax number will be 571-273-0893.***



Lorraine Spector, Ph.D.
Primary Examiner